

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 102004062775	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2005/013742	International filing date (day/month/year) 20.12.2005	Priority date (day/month/year) 21.12.2004
International Patent Classification (IPC) or national classification and IPC A01N31/02		
Applicant STOCKHAUSEN GMBH		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>17</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on:



the international application in the language in which it was filed



the translation of the international application into _____, which is the language of a translation furnished for the purposes of:



international search (Rule 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rule 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished



the description:

pages 1-12 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19
21.12.2006 withnos.* 1-13 received by this Authority on telefax

nos.* _____ received by this Authority on _____



the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

the description, pages _____



the claims, nos. _____



the drawings, sheets/figs _____

the sequence listing (*specify*): _____any table(s) related to sequence listing (*specify*): _____4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages _____



the claims, nos. _____



the drawings, sheets/figs _____

the sequence listing (*specify*): _____any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																					
1. Statement	<table><tr><td rowspan="2">Novelty (N)</td><td>Claims</td><td>_____</td><td>YES</td></tr><tr><td>Claims</td><td>1-13</td><td>NO</td></tr><tr><td rowspan="2">Inventive step (IS)</td><td>Claims</td><td>_____</td><td>YES</td></tr><tr><td>Claims</td><td>1-13</td><td>NO</td></tr><tr><td rowspan="2">Industrial applicability (IA)</td><td>Claims</td><td>1-13</td><td>YES</td></tr><tr><td>Claims</td><td>_____</td><td>NO</td></tr></table>	Novelty (N)	Claims	_____	YES	Claims	1-13	NO	Inventive step (IS)	Claims	_____	YES	Claims	1-13	NO	Industrial applicability (IA)	Claims	1-13	YES	Claims	_____	NO
Novelty (N)	Claims		_____	YES																		
	Claims	1-13	NO																			
Inventive step (IS)	Claims	_____	YES																			
	Claims	1-13	NO																			
Industrial applicability (IA)	Claims	1-13	YES																			
	Claims	_____	NO																			
2. Citations and explanations (Rule 70.7)	<p>Reference is made to the following international search report citations (D1 to D5):</p> <p>D1: US 2002/127253 A1</p> <p>D2: US-A-4 511 486</p> <p>D3: US-A-5 167 950</p> <p>D4: SANDERS P A: "AQUEOUS ALCOHOL FOR AEROSOL FOAMS" DRUG AND COSMETIC INDUSTRY, <u>99</u>(2), pages 56, 58, 60, 142, 143, 146-154 (1996)</p> <p>D5: WO 03/028671 A.</p> <p>Irrespective of the objections to the claims raised under PCT Article 5 and 6 (see Box VIII below), the subject matter of the claims as interpreted in Box VIII is not novel and, insofar as it is novel, would appear not to involve an inventive step.</p> <p>Novelty</p> <p>The subject matter of claims 1-13 is not novel (PCT Article 33(1) and (2)).</p>																					

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	<p>Independent claim 1, whose subject matter corresponds to the preferred embodiment of claim 8 as originally filed, concerns a pumping foam formulation in the form of an alcoholic foam composition containing at least 52-99% by weight alcohol, at least one silicone surfactant or a fluorosurfactant, or a mixture of fluorosurfactants and silicone surfactants, and a polyalkylene glycol. A further feature, that is to say, the fact that the surfactant exhibits a surface tension of around ± 15 dyn/cm of the surface tension of the alcoholic component, cannot be taken into consideration for the reasons given in Box VIII, point 2, since it is considered to be a feature of any surfactant-alcohol mixture.</p> <p>Additional features of dependent claims include the surface tension of the surfactant (claim 2; this parametric statement is treated like the one above), specify the alcohol more closely (claims 3 and 4), and give the content of alcohol, surfactant (claims 5, 6 and 7), polyalkylene glycol (claim 8) and optional foam stabilizer (claim 9).</p> <p>Independent claim 10 relates to the use of the foam compositions as disinfectants. Claims 11-13, which are considered dependent claims and should therefore have been worded in compliance with PCT Article 6 in combination with PCT Rule 6.4a, describe the material to be disinfected in more detail.</p> <p>Document D1 discloses (see the passages cited in the international search report) disinfectants containing 35-95% ethanol, a combination of emulsifiers which also</p>

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	<p>serve as viscosity-improving agents, and superfatting agents such as polyalkylene glycols and polysiloxanes. The addition of dimethicone copolyol surfactants such as, for example, ABIL[®] 88183, also mentioned in the present application as one of the especially well suited silicone surfactants of the ABIL[®] B88 range, is further said to be advantageous. The formulations can be used to produce foams. The production of an aerosol foam is described. Since the composition contains all the components of a foam composition according to claim 1, it follows that, provided (see Box VIII below) the components defined are sufficient to obtain a formulation which can be applied in the form of a pumping foam, it also has to be suitable for this kind of application that is to say, be a pumping foam formulation. The disclosure in document D1 is therefore considered prejudicial to the novelty of all the claims.</p> <p>Document D2 discloses (see the passages cited in the international search report) a non-pressurized, rapidly collapsing foam for cleaning dentures. The formulations contain 35-70% alcohol, surfactants and humectants such as, for example, polyethylene glycol. Document D2 states that the latter stabilizes the foam and therefore makes it possible to control the period of time until the foam collapses. The use of silicone surfactants or fluorosurfactants is not suggested. Consequently, the disclosure in document D2 is not prejudicial to novelty.</p> <p>Document D3 discloses (see the passages cited in the international search report) formulations with a high alcohol content which together with foaming agents yield</p>

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a stable antimicrobial foam which collapses only upon friction and contact. The mixture contains 52-75% ethanol or isopropanol, a thickening agent on a polyacrylic acid or cellulose derivative basis, a C₁₆-C₂₂ alcohol and a polyethoxylated non-ionic surfactant. The addition of a polyalkylene glycol is not mentioned. Consequently, document D2 is not prejudicial to the novelty of the subject matter of the application.

Document D4 describes (see the passages cited in the international search report) the basic principles to be observed when formulating aqueous, alcoholic aerosol foams. It explains that only very few surfactants are suitable for formulations with a high alcohol content. None of the mixtures examined uses polyalkylene glycol.

Lastly, document D5 discloses (see the passages cited in the international search report) a surfactant combination particularly suitable for the production of especially pumping foams. It does not make reference to foams with a high alcohol content.

Inventive step

1. Even if it were novel, the subject matter of claims 1-13 would still not be considered to involve an inventive step (PCT Article 33(1) and (3)).

In the light of the description and of document D3, which is considered the closest prior art, the problem to be solved is that of providing stable foams having a high alcohol content of at least 52%, for disinfection.

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Document D2 is not the closest prior art document.

Although the composition described in document D2 has a feature in common with the subject matter of the amended claim, that is to say, it is intended to be dispensed without propellant, it does not contain the decisive feature, which is the high alcohol content of more than 52%. In addition, the stated problem of document D2, that is to say, to produce rapidly collapsing foams, is completely different from that of the present application, which aims to produce high-volume foams that do not collapse.

As regards independent claim 1, the difference between the subject matter of the claim of the present application and the disclosure in the closest prior art document D3 lies in the choice of fluorosurfactants or silicone surfactants, the suitability for delivery as a pumping foam, and the addition of polyalkylene glycol.

If one accepts the implied assumption of the description of the application (see Box VIII), according to which almost any surfactant can be used and the adjustment of these surfactants to the foam production method is routine, the choice of surfactant and the production method does not involve an inventive step.

The description expressly states (see page 7, lines 8 and 9) that "every surfactant or surfactant mixture that satisfies the above specification [that is to say, that of surface tension], is suitable as component b) of the foam composition according to the invention." When carrying out the technical teaching a person skilled in

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the art will invariably have to choose a surfactant. In accordance with the "could-would approach" a person skilled in the art could, for example, choose silicone surfactants. In view of the large number of possible surfactants, it is unlikely that a person skilled in the art would choose precisely silicone surfactants. However, what is decisive is not the mere probability of the selection but whether such a choice would have been made in the hope of solving the technical problem or of obtaining an additional advantage. No additional advantage is claimed, and since it is obvious from the above statement that "any surfactant" can be selected in order to solve the problem of interest, the selection of precisely silicone surfactants or fluorosurfactants cannot be considered to make an inventive contribution to the prior art.

It is further known from document D2 that the stability of foams dispensed without pressure can be controlled using polyalkylene glycols.

If, contrary to the statements made in Box VIII below, one proceeds from the assumption that all formulations encompassed by the scope of claims 1 to 10 actually solve the problem of interest, none of claims 1 to 10 can involve an inventive step. The more specific solutions of the dependent claims, including solutions which would result from a combination of features of several dependent claims, would merely constitute some of the many possibilities from which a person skilled in the art would be able to choose. In that case the subject matter outlined in Box VIII, point 3.5, would be the result of

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nothing more than a choice of this kind, which would be straightforward and would not involve inventive skill.

2. On the other hand, if on the basis of the statements in Box VIII one were to assume that to solve the problem of interest it is indeed necessary to choose each one of the different components of the above kind of formulation in such a way that a balance is struck between what in some respects are contradictory requirements, a successful solution to the problem of interest would point to an inventive step, since in that case the possible choices would be very limited and complex.

If the above assumption applies, the subject matter defined in Box VIII, point 3.5, could be considered to involve an inventive step.

Industrial applicability

The subject matter of claims 1-13 is considered industrially applicable (PCT Article 33(1) and (4)).

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The application does not meet the requirements of PCT Article 5 and 6.

1.1 It is assumed that the expression alcoholic "foam compositions" relates not only to already foamed compositions but also to foamable compositions.

1.2 The term foam stabilizers is extremely vague and states only what is clearly a desirable property of every component of such a composition. Unless expressly stated otherwise, every component, and in particular every surfactant and thickening agent, is therefore considered to exhibit this property.

2. Claim 1 specifies the decisive feature according to which the surfactant has a surface tension of around ± 15 mN/m [± 15 dyn/cm] of the surface tension of the alcoholic component.

2.1 This feature is not sufficiently clear (PCT Article 6). It is not clear to which surface it relates, but presumably it concerns the surface tension relative to air. It is further not clear whether the figures are intended to express the surface tension of the pure substances, that is to say, of the alcohols and surfactants, of mixtures thereof with water and, if the latter is the case, in which concentration (for example, 0.1%, 1%), or of the finished composition. In addition, in the case of octanol, for example, it would not be possible to determine the surface tension of the finished

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composition, owing to its poor water solubility.

Moreover, the measured surface tension also depends on temperature and the measurement method used. No measurement method is specified. However, even if one had been given, this would not have been sufficient to overcome the defects mentioned above. For example, DIN EN 14370:2004 defines neither the temperature nor the concentration.

2.2 It follows from the relative surface tension given in claim 1 and the absolute surface tension of 20-40 mN/m given in claim 2 that in preferred compositions the alcohols are intended to have a surface tension of between 5 and 55 mN/m. This is the range in which the surface tension of almost all liquid organic compounds is situated. The surface tension of the vast majority of surfactants (in water) is also likely to be situated in the above range, with silicone surfactants and fluorosurfactants being close to, or even below (!), the lower limit. If one further takes into consideration the fact that water has a surface tension of approximately 70mN/m, it would be reasonable to expect that a considerable portion, if not most, of all conceivable surfactant-alcohol combinations, whether present as pure substances or as aqueous solutions, meets the parametric conditions of claims 1 and 2.

In other words, as regards the surfactants, the above requirement does not constitute a narrow selection from a large number of possibilities but excludes only a few, in any event extreme, combinations.

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A substantial portion of precisely the silicone surfactants and fluorosurfactants selected in the amended claims might be situated below the chosen range, and hence the lack of clarity of this feature and of its restrictive effect is especially severe.

2.3 For the above reasons it is assumed that any possibly combination of standard alcohols and standard silicone surfactants or fluorosurfactants meets the unclear conditions of claims 1 and 2 regarding relative and absolute surface tension.

3.1 The application specifies three examples of foam compositions according to the invention (last table on page 12 of the description). Apart from water these compositions all contain:

- a) 55-90% ethanol as the alcohol,
- b) 3.0-4.0% Bis-PEG/PPG-20/20-dimethicone as surfactant,
- c) polyethylene glycol (PEG-14M) as the polyalkylene glycol, at a concentration of 0.05-0.1%, and
- d) ethyl cellulose polymer, as a foam stabilizer, at a concentration of 0.1-0.2%.

No statement is made regarding relative or absolute surface tension.

The first table on page 12 does not give specific examples but merely specific quantities concerning generic information on the component classes. Examples" A, D and E would appear to correspond to the three

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examples of these classes.

3.2 Consequently, the examples (assuming that they satisfy the parametric conditions) represent a combination of all the features of claims 1, 2, 5 and 7-9, to which, in the case of claims 5, 7 and 9, further defining features are added.

In contrast, claim 1 is based on generalizations, that is to say, it suggests that several of the more specific features are not necessary to solve the problem and can be replaced with more general ones or even dispensed with altogether. However, claim 1 does not give examples in support of this; it merely states that the surfactant must belong to the class of surfactants used in the examples, or be a fluorosurfactant.

However, according to the claim, a feature not even mentioned in the examples, that is to say, the fact that the relative surface tension of the surfactant is situated in a specific range, is a further absolutely essential and decisive feature.

More precisely, the following generalizations are found:

- a) instead of 55-90% ethanol, any alcohol or alcohol mixture can be used, at concentrations of 52-99%;
- b) instead of 3.0-4.0% Bis-PEG/PPG-20/20-dimethicone, any quantity of any silicone surfactant or a fluorosurfactant can be used, provided an unclear parametric condition is satisfied;
- c) instead of 0.05-0.1% PEG-14M, any quantity of any

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- polyalkylene glycol can be used, and
- d) (0.1-0.2%) ethyl cellulose polymer can be dispensed with altogether.

3.3 The description offers no explanation as to a possible basis for the generalizations that lead to the subject matter of the claims.

3.3.1 The amended claims imply that the applicant wishes to move away precisely from the explicit statement in the description that every surfactant is suitable (see page 7, lines 8 and 9) and that instead surfactants have to be chosen which are situated near the upper or lower limits of the specified surface tension range.

In contrast, the implied statement that any alcohols and polyalkylene glycols can be chosen and that precisely the stabilizing thickening agent is optional is maintained.

The observed tendency of the foams to be unstable is clearly the result on interactions between the components, for example (see the description, page 6, paragraph 1), the fact that the alcohol acts as a solvent. It follows that the interacting components must be adjusted to each other; for example the surfactant must be adjusted to the alcohol, and vice versa. It is not clear why precisely the choice of a particular class of surfactants might make it possible to freely choose all the other components.

3.3.2 The above basic assessment is not altered by the fact that the subject matter of the application is

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now restricted to pumping foam formulations. The pumping foam formulation may require specific adjustments different from those needed for a formulation as an aerosol foam. However, the description states only that the pumping foam formulations are preferred and therefore implies that aerosol foams can also be made using the specified formulation and that the necessary specific adjustment require only routine measures. Even if this was not the case, it is still obvious that the technical difficulties arising from the interactions of the components, for example the effect of the alcohols used as solvents, change depending on the way in which the foam is produced but do not disappear altogether with any one method.

3.3.3 The general technical knowledge of a person skilled in the art likewise does not contain a basis for the above kind of far-reaching generalizations.

The prior art document D4 concerns complex interactions affecting the stability of aqueous alcoholic aerosol foams. It states that only very few surfactants are suitable for formulations with a high alcohol content and that the behaviour of these foams depends, *inter alia*, on the alcohol and the other components used. This is a statement of fact, which for the above reasons, should in principle also apply to pumping foams, even if the surfactants suitable for such foams might be different from those used in aerosol foams.

Whether this statement is true or false does not depend on the date of publication of document D4, the solutions

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suggested therein or whether or not certain surfactants were already known at the time of publication. Document D4 merely illustrates that the explicit claim (see the description) that every surfactant would be suitable and the implied claim that every alcohol and every polyalkylene glycol would also be suitable, has no basis in the general knowledge in the art. It is clear that these claims are not supported by the remainder of the description (see points 3.1 and 3.2 above).

It would appear that through the amended claim 1 the applicant would now like to distance himself from these claims as regards the surfactant, but that he maintains the claims with regard to the other components.

The applicant's attention is drawn to the fact that his implied assumption that a successful solution of the technical problem of providing stable alcoholic foam compositions points to an inventive step assumes that the behaviour of such systems can be anticipated to only a very limited extent; this in turn excludes far-reaching generalizations.

Consequently, the subject matter of the claim is not supported by the description (PCT Article 6) and it can be assumed that it is largely unable to solve the problem of interest and hence does not meet the requirements of PCT Article 6.

3.4 Should claim 1 further include solutions to the problem of interest other than those shown in the examples and the resulting reasonable generalizations

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(see below), these additional solutions would not be sufficiently disclosed (PCT Article 5).

3.5 A subject matter based on reasonable generalizations, which therefore satisfies PCT Article 5 and 6, is found only in the description (page 9, paragraph 2) in the form of the preferred of the preferred embodiments:

- a) 55-96% by weight ethanol,
- b) 1-10% by weight Bis-PEG/PPG-20/20-dimethicone,
- c) 0.05-2% by weight polyethylene glycol, chosen from PEG 7M - PEG 45M, and
- d) 0.05-3% by weight ethyl cellulose polymer.